UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHIRE LLC, **Plaintiff,** **v.** **TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,** **Defendants.**	**Civil Action No. 07 Civ. 3526 (MGC)**

SHIRE LLC'S REPLY TO TEVA PHARMACEUTICALS USA, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S AMENDED COMPLAINT

Plaintiff, Shire LLC ("Shire"), by its attorneys, replies herein to the averments made in the numbered paragraphs of the first counterclaim asserted by defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"). This reply concerns only Teva USA's first counterclaim as Teva USA has voluntarily moved to dismiss its Counterclaim II direct to U.S. Patent No. 5,912,013.

THE PARTIES

1. Counterclaim: On information and belief, Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

Reply: Shire admits the allegations of paragraph 1.

2. Counterclaim: Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

Reply: Shire admits the allegations of paragraph 2.

JURISDICTION AND VENUE

3. Counterclaim: This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202.

Reply: With regard to paragraph 3, Shire admits only that subject matter jurisdiction of this action exists pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202. Shire denies all remaining allegations of paragraph 3.

4. Counterclaim: Personal jurisdiction of Plaintiff is proper by virtue of, *inter alia*, Plaintiff submitting to jurisdiction of this Court through the filing of the present Complaint

Reply: Shire admits the allegations of paragraph 4.

5. Counterclaim: Subject matter jurisdiction over these controversies is proper under 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202.

Reply: Shire admits the allegations of paragraph 5.

6. Counterclaim: Venue is proper under 28 U.S.C. §§ 1391 and 1400, and 21 U.S.C. § 355(j)(5)(B)(iii)(III).

Reply: With respect to paragraph 6, Shire admits only that venue is proper in the Southern District of New York. Shire denies all remaining allegations of paragraph 6.

BACKGROUND

7. Counterclaim: Teva USA submitted Abbreviated New Drug Application ("ANDA") No. 78-592 ("Teva's ANDA") with the United States Food and Drug Administration ("FDA") for carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths ("Teva USA's carbamazepine products").

Reply: Shire admits the allegations of paragraph 7.

8. Counterclaim: Shire has caused U.S. Patent Nos. 5,326,570 ("the '570 patent") and 5,192,013 ("the '013 patent) to be listed in the FDA "Approved Drug Products with

Therapeutic Equivalence Evaluation" ("commonly known as the "Orange Book") in connection with its NDA No. 20-712 relating to carbamazepine capsules.

Reply: With respect to paragraph 8, Shire admits only that the '570 and '013 patents are listed in the Orange Book as covering Shire's Carbatrol® drug products. Shire denies all remaining allegations of paragraph 8.

9. Counterclaim: By submitting the '570 patent and the '013 patent for inclusion in the FDA Orange Book, Shire has indicated that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21. [sic] U.S.C. § 355(b)(1).

Reply: With respect to paragraph 9, Shire admits only that the '570 and '013 patents are listed in the Orange Book as covering Shire's Carbatrol® drug products. Shire denies all remaining allegations of paragraph 8.

10. Counterclaim: Teva USA seeks FDA approval to market its generic carbamazepine products before expiration of the patents Shire listed in the Orange Book" [sic] Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva USA's ANDA includes a paragraph IV certification to the '570 patent and the '013 patent.

Reply: Shire admits the allegations of paragraph 10.

11. Counterclaim: Under 21 U.S.C. § 355(j)(2)(B)(i) and (ii), Teva USA provided Shire with notice that it made a paragraph IV certification with the FDA ("ANDA notice"). The ANDA notice included a detailed statement in which Teva USA set forth the bases for its position that the manufacture, use, or sale of Teva USA's carbamazepine products will not infringe any claims of the '570 and '013 patents.

Reply: With respect to paragraph 11, Shire admits only that Teva USA provided Shire with a notice that it made a paragraph IV certifications to the '570 and '013 patents. Shire denies all remaining allegations of paragraph 11.

12. Counterclaim: On information and belief, Shire received Teva USA's ANDA notice. With this notice, Teva USA offered Shire confidential access to its ANDA so that Shire could determine for itself that Teva USA's carbamazepine products would not infringe the '570 and '013 patents.

Reply: With respect to paragraph 12, Shire admits only that Shire received Teva USA's ANDA notice, and that Teva USA offered Shire confidential access to its ANDA. Shire denies all remaining allegations of paragraph 12.

13. Counterclaim: Under 21 U.S.C. § 355(j)(2)(B)(iii) and 35 U.S.C. § 271(e)(5), Teva USA was precluded from bringing a declaratory judgment action for 45 days after Shire received Teva USA's ANDA notice.

Reply: With respect to paragraph 13, Shire admits only that 21 U.S.C. § 355(j)(2)(B)(iii) provides that "An applicant required under this subparagraph to give notice shall give notice to -- (I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and (II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice;" and that 35 U.S.C. § 271(e)(5) provides that "Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the

approved application under subsection (b) of such section of the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 of a declaratory judgment that such patent is invalid or not infringed." Shire denies all remaining allegations of paragraph 13.

14. Counterclaim: More than 45 days have now passed since Shire received Teva USA's ANDA notice.

Reply: Shire admits the allegations of paragraph 14.

15. Counterclaim: On May 2, 2007, within that 45 day period, Shire sued Teva USA alleging infringement of the '570 and the '013 patents.

Reply: With regard to paragraph 15, Shire admits that on May 2, 2007, Shire filed a complaint alleging infringement of the '570 and '013 patents. Shire denies all remaining allegations of paragraph 15.

16. Counterclaim: On August 24, 2007, Shire amended its complaint. The amended complaint alleges infringement of the '570 patent but not the '013 patent.

Reply: With regard to paragraph 16, Shire admits that the amended complaint, filed August 23, 2007, alleges infringement of the '570 patent but not the '013 patent. Shire denies all remaining allegations of paragraph 16.

COUTERCLAIM I
DECLARATION OF NON-INFRINGEMENT OF THE '570 PATENT

17. Counterclaim: Teva USA realleges and incorporates by reference the allegations of paragraphs 1-16.

Reply: With respect to paragraph 17, Shire repeats and incorporates by reference paragraphs 1-16 of the reply.

18. Counterclaim: This claim arises under the Patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory judgment [sic] Act, 28 U.S.C. §§ 2201 and 2202, and 21. [sic] USC. [sic] § 355(j)(5)(C) ("Civil Action to Obtain Patent Certainty").

Reply: Shire admits the allegations of paragraph 18.

19. Counterclaim: There is an actual controversy between Teva USA and Plaintiff concerning the issue of whether Teva USA's prospective manufacture, use, offer for sale, or sale of Teva USA's carbamazepine products will infringe claims of the '570 patent.

Reply: Shire admits the allegations of paragraph 19.

20. Counterclaim: Based on Shire's listing of the '570 patent in the Orange Book, Teva USA's paragraph IV certification of the '570 patent, and the circumstances between Teva USA and Plaintiff with respect to the '570 patent, the parties' respective interest are adverse and sufficiently definite and concrete so as to warrant a declaratory judgment.

Reply: Shire's admits the allegations of paragraph 20.

21. Counterclaim: Teva USA is entitled to a declaratory judgment that the manufacture, use, offer for sale, or sale of Teva USA's carbamazepine products will not infringe any claim of the '570 patent.

Reply: Shire denies the allegations of paragraph 21.

COUNTERCLAIM II
DECLARATION OF NON-INFRINGEMENT OF THE '013 PATENT

22. Counterclaim: Teva USA realleges and incorporates by reference the allegations of paragraphs 1-21.

Reply: With respect to paragraph 22, Teva USA has voluntarily moved to dismiss its Counterclaim II directed to the '013 patent. Accordingly, no reply is necessary.

23. Counterclaim: The claim arises under the Patent laws of the United Stats, 35 U.S.C. § 1 et seq., and the Declaratory judgment [sic] Act, 28 U.S.C. §§ 2201 and 2202, and 21. [sic] USC. [sic] § 355(j)(5)(C) ("Civil Action to Obtain Patent Certainty").

Reply: With respect to paragraph 23, Teva USA has voluntarily moved to dismiss its Counterclaim II directed to the '013 patent. Accordingly, no reply is necessary.

24. Counterclaim: Under 21 U.S.C. § 355(j)(5)(C) ("Civil Action to Obtain Patent Certainty"), Teva USA is entitled to a determination that the '013 patent is not infringed by Teva's ANDA application.

Reply: With respect to paragraph 24, Teva USA has voluntarily moved to dismiss its Counterclaim II directed to the '013 patent. Accordingly, no reply is necessary.

25. Counterclaim: In addition, based upon Shire's listing of the '013 patent in the Orange Book and Teva USA's submission of an ANDA with a paragraph IV certification directed to the '013 patent, the parties' respective interests are adverse and sufficiently definite and concrete so as to warrant a declaratory judgment.

Reply: With respect to paragraph 25, Teva USA has voluntarily moved to dismiss its Counterclaim II directed to the '013 patent. Accordingly, no reply is necessary.

26. Counterclaim: Teva USA is entitled to a declaration that the manufacture, use, offer for sale, or sale of Teva USA's carbamazepine products will not infringe any claim of the '013 patent.

Reply: With respect to paragraph 26, Teva USA has voluntarily moved to dismiss its Counterclaim II directed to the '013 patent. Accordingly, no reply is necessary.

RELIEF

WHEREFORE, Shire respectfully requests that the Court:

(a) grant the relief sought in Shire's amended complaint;

(b) deny the relief sought in Teva USA's counterclaim; and

(c) deny Teva USA any other relief.

FROMMER LAWRENCE & HAUG LLP

Dated: November 6, 2007

By: _____

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CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of November, 2007, a copy Shire LLC's Reply to Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative Defenses and Counterclaims to Plaintiff's Amended Complaint was delivered by email to:

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